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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,898	03/07/2005	Eiji Tsuru	Q86527	7841

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SUGHRUE MION, PLLC  
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SUITE 800  
WASHINGTON, DC 20037

EXAMINER

KOSACK, JOSEPH R

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/526,898

Applicant(s)

TSURU ET AL.

Examiner

Joseph Kosack

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 03/07/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-17 are pending in the instant application.

#### ***Priority***

The claim to priority to PCT/JP03/11345, filed on September 5, 2003, which claims priority to JP 2002-262157, filed on September 6, 2002 has been acknowledged in the instant application.

#### ***Information Disclosure Statement***

The Information Disclosure Statement filed on March 7, 2005 has been considered fully by the examiner.

#### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Crystal of KMD-3213 and Solid Formulation for Treatment of Dysuria.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

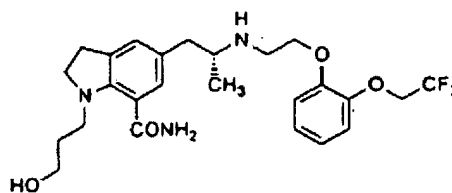
Art Unit: 1626

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

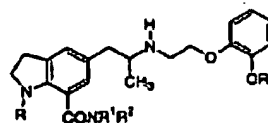
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP07-330726A) in view of Williamson (*Macroscale and Microscale Organic Experiments* 1999, pages 39 and 48-50).

The instant application teaches a crystal of:  
with a particular X-ray diffraction pattern.



Determination of the scope and content of the prior art (MPEP §2141.01)



Yamagishi et al. teach a compound of formula: , where R is hydroxypropyl, R1 and R2 are hydrogen, and R3 is trifluoroethyl, and its crystallization. See Reference Example 30, page 24, paragraph 184.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Yamagishi et al. do not teach the X-ray diffraction pattern of their crystals or the explicit crystallization using the method described in page 5, lines 24-29 of the specification.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Yamagishi et al. teach the dissolving of crude crystals in heated ethyl acetate, and allowing the solution to stand at room temperature. See Reference Example 30, page 24, paragraph 184.

Williamson teaches the gradual cooling of a heated saturated solution to room temperature to induce crystallization. See pages 48-50.

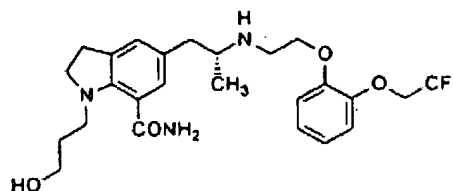
Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to take the procedure of Yamagishi et al. and use the guidance of Williamson to make the crystals of the instant invention, with a reasonable expectation of success. Since the crystals are prepared in the same manner as that of the instant application on page 5, lines 24-29 of the specification, the crystals made in this manner inherently have the same X-ray diffraction pattern as that

Art Unit: 1626

of the instant invention. The motivation to do so is provided by Williamson. Williamson teaches that crystallization is the most important method for the purification of solid organic compounds. See page 39.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

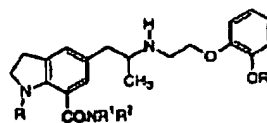
Claims 2-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP07-330726A) in view of Williamson (*Macroscale and Microscale Organic Experiments* 1999, pages 39 and 48-50) and Kitazawa et al. (USPN 5,387,603).



The instant application teaches a crystal of:

with a particular X-ray diffraction pattern.

Determination of the scope and content of the prior art (MPEP §2141.01)



Yamagishi et al. teach a compound of formula:

, where R is

hydroxylpropyl, R1 and R2 are hydrogen, and R3 is trifluoroethyl, and its crystallization.

See Reference Example 30, page 24, paragraph 184.

Ascertainment of the difference between the prior art and the claims (MPEP

§2141.02)

Yamagishi et al. do not teach the X-ray diffraction pattern of their crystals or the explicit crystallization using the method described in page 5, lines 24-29 of the specification.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Yamagishi et al. teach the dissolving of crude crystals in heated ethyl acetate, and allowing the solution to stand at room temperature. See Reference Example 30, page 24, paragraph 184.

Williamson teaches the gradual cooling of a heated saturated solution to room temperature to induce crystallization. See pages 48-50.

Kitazawa et al. teaches a pharmaceutical composition containing as an active ingredient the compound of Yamagishi et al. See column 15, line 41 through column 16, line 23 and column 62, line 51, through column 64, line 15.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to take the procedure of Yamagishi et al. and use the guidance of Williamson to make the crystals of the instant invention, and convert to any pharmaceutical composition with the instant invention as an active ingredient as taught by Kitazawa et al., with a reasonable expectation of success. Since the crystals are prepared in the same manner as that of the instant application on page 5, lines 24-29 of the specification, the crystals made in this manner inherently have the same X-ray diffraction pattern as that of the instant invention. The motivation to do so is provided by

Williamson. Williamson teaches that crystallization is the most important method for the purification of solid organic compounds. See page 39.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

### ***Double Patenting***

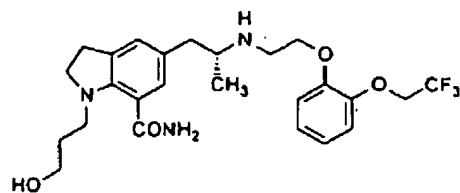
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-17 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 of U.S. Patent No. 5,387,603 in view of Yamagishi et al. (JP07-330726A) and Williamson (*Macroscale and Microscale Organic Experiments* 1999, pages 39 and 48-50).

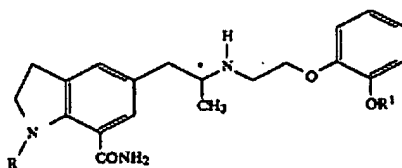




The instant application teaches a crystal of:  
with a particular X-ray diffraction pattern.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kitazawa et al. teaches a pharmaceutical composition containing as an active



ingredient a compound of formula:

with R as

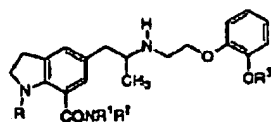
hydroxypropyl and R<sup>1</sup> as trifluoroethyl. See claims 12 and 13.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kitazawa et al. do not teach the crystallization of the compound, nor its X-ray diffraction pattern.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Yamagishi et al. teach the dissolving of crude crystals of formula:



, where R is hydroxypropyl, R<sup>1</sup> and R<sup>2</sup> are hydrogen, and R<sup>3</sup> is

trifluoroethyl in heated ethyl acetate, and allowing the solution to stand at room temperature. See Reference Example 30, page 24, paragraph 184.

Williamson teaches the gradual cooling of a heated saturated solution to room temperature to induce crystallization. See pages 48-50.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to take the procedure of Yamagishi et al. and use the guidance of Williamson to make the crystals of the instant invention, and convert to any pharmaceutical composition with the instant invention as an active ingredient as taught by Kitazawa et al., with a reasonable expectation of success. Since the crystals are prepared in the same manner as that of the instant application on page 5, lines 24-29 of the specification, the crystals made in this manner inherently have the same X-ray diffraction pattern as that of the instant invention. The motivation to do so is provided by Williamson. Williamson teaches that crystallization is the most important method for the purification of solid organic compounds. See page 39.

### ***Conclusion***

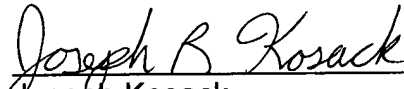
Claims 1-17 are rejected.

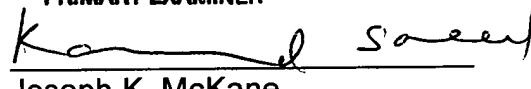
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph Kosack  
Patent Examiner  
Art Unit 1626

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for Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626